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OCT 6 - 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy Orthopaedics, Inc.
P.O. Box 988
709 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT:

Natalie Heck
Manager, Regulatory Affairs
Tel: (574) 372-7469
Fax: (574) 371-4987

TRADE NAME:

DePuy Global™ Shoulder Crosslink Glenoid

COMMON NAME:

Shoulder Prosthesis

CLASSIFICATION:

888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II

DEVICE PRODUCT CODE:

KWS

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Global™ Shoulder Glenoid – K981487
DePuy Global™ Shoulder – K914000
DePuy Sigma XLK Tibal Inserts – K040166

DEVICE DESCRIPTION:

The DePuy Global™ Crosslink Glenoids are offered in an anchor peg and a fin design. The Crosslink Glenoid anchor peg design consists of six sizes: 40mm, 44mm, 48mm, 52mm, 56mm and 56mmXL. The Crosslink Glenoid in the fin design consists of seven sizes: 40mmXS, 40mm, 44mm, 48mm, 52mm, 56mm and 56mmXL. Both the anchor peg and fin designs have a lateral surface that is concave and designed to articulate with the DePuy Global™ line humeral heads indicated for use in total shoulder arthroplasty. The fixation surface has a central fin or peripheral pegs and is intended to be attached to the glenoid fossa of the scapula with bone cement.

INTENDED USE:

The Crosslink Glenoids are intended for use in total shoulder replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, trauma or failed prior surgical intervention.

The Crosslink Glenoids are intended for cemented use only.

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BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Global™ Crosslink Glenoids have the same design, intended use and indications as the Glenoid components cleared in K981497 and K914000 as part of DePuy's Global Shoulder System. The difference between the Crosslink Glenoids proposed in this submission and the Glenoids in the Global Shoulder System is the type of polyethylene used to manufacture the components. The Crosslink Glenoids are made from highly cross-linked polyethylene, which has been to shown to have a reduction in wear compared to currently available Enduron polyethylene. The Crosslink Glenoids are made from the same cross-linked polyethylene as that cleared in the DePuy Sigma XLK Tibial Inserts, listed in K040166. Due to the similarities noted DePuy believes the Crosslink Glenoids to be substantially equivalent in design to the Glenoids of DePuy Global Shoulder System and in material to the DePuy Sigma XLK Tibial Inserts, with the additional claim of reduced wear, based on results of shoulder simulator wear studies of these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2005

Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K052472
Trade/Device Name: DePuy Global™ Shoulder Crosslink Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: September 3, 2005
Received: September 8, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052472

Device Name: DePuy Global™ Shoulder Crosslink Glenoid

Indications for Use:

The Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.

2. Fracture-dislocations of the proximal humerus where the articular surface is severely communited, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.

3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

Glenoid components are intended for cemented use only.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052472 0000005